MAR 1 4 2014

510(k) SUMMARY

Prosidyan, Inc.'s BG Morsels – Bone Graft Substitute

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Prosidyan, Inc.
3 Rosemont Court
Basking Ridge, NJ 07920
Phone: (908) 326-6263
Contact Person: Charanpreet S. Bagga

Date Prepared: February 27, 2014

Name of Device and Name

BG Morsels Bone Graft Substitute

Common or Usual Name

Bone Void Filler

Classification Name/CFR Regulation/Product Code

Resorbable Calcium Salt Bone Void Filler, 21 CFR 888.3045, product code MQV, Class II

Predicate Devices

NovaBone Products, LLC's NovaBone Resorbable Bone Graft Substitute (K052494) and NovaBone Putty (K112773)

Intended Use / Indications for Use

BG Morsels - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. BG Morsels is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

BG Morsels is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Technological Characteristics

BG Morsels provides an osteoconductive, resorbable, biocompatible bone graft substitute made from crystalline 45S5 bioactive glass. Each granule of BG Morsels is created from a matrix of bioactive glass fibers and microspheres. Bioactive glass is defined as a group of glasses which has a compositional range that allows the formation of hydroxyapatite (HA) as a surface layer when exposed to an aqueous phosphate-containing solution such as simulated body fluid. The HA layer that forms in an aqueous phosphate-containing solution plays a significant role in forming a strong bond with natural bone. The granules provide an

ultra-porous scaffold for desired biological response and improved handling characteristics, while optimizing radiopacity and resorption. BG Morsels are generally spherical in appearance and provided in granular form. The matrix is flash sintered to form a porous shell at its surface, which creates the generally spherical structure of the granules, while maintaining a level of porosity within each granule.

Performance Data

Physical property evaluations, functional animal studies, and biocompatibility tests were performed for the BG Morsels device. Specifically, simulated distribution, whole package integrity and seal strength were tested on the defined packaging configuration. Accelerated and real time aging tests were also performed with passing results. The biocompatibility of the BG Morsels is demonstrated by ISO 10993 testing and the long history of clinical use of the bioactive glass material for the same intended use. In addition, the BG Morsels is composed of the same bioactive glass material with the same chemical composition and the same type and duration of patient contact as the NovaBone predicates. The physical functions and bioactivity of the BG Morsels were also evaluated, and results met the testing requirements. The device is considered bioactive based on *in vitro* studies that show apatite layer formation on the surface of the implant following immersion in simulated body fluid (SBF). These results have not been correlated to clinical performance.

Animal testing demonstrated evidence of new bone formation in critical size defects, consistent with FDA's recommendations for Class II synthetic bone graft substitutes. The Prosidyan BG Morsels product was evaluated and compared to a positive control, the predicate device (NovaBone Putty), and to a negative sham control (untreated defect) in an ovine model. The animal study evaluated the device performance in critical sized cancellous bone defects in the lateral distal femurs from 58 skeletally mature sheep, including radiographic, histological, histomorphometric, and biomechanical data. Testing of the BG Morsels in the ovine model is representative of the indications for use and range of anatomical sites proposed for the subject device. In addition, the study was conducted for a duration of 24 weeks with several interim evaluation points (i.e., 4, 8, 12, and 24 weeks), including a minimum of 3 animals per time point per treatment group. The results of the study demonstrated that the BG Morsels device performs as safely and as effectively as the predicate device, and any differences between the results of the device groups do not raise new types of safety or effectiveness concerns.

Therefore, performance testing demonstrated that the BG Morsels device functions as intended and meets the requirements of class II bone void fillers as compared to the predicate devices.

Substantial Equivalence

BG Morsels is as safe and effective as the NovaBone predicate devices. BG Morsels has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between BG Morsels and its predicate devices do not raise any new issues of safety or effectiveness. Performance data demonstrate that BG Morsels is as safe and effective as the NovaBone predicate devices. Thus, BG Morsels is substantially equivalent.

Conclusion

The BG Morsels is an osteoconductive, resorbable, biocompatible bone graft substitute composed of crystalline bioactive glass. The BG Morsels is as safe and as effective as its

predicate devices for its intended use as a synthetic bone void filler, and is substantially equivalent to the predicate devices. Performance testing, including in vivo data, demonstrated that the device functions as intended without raising new safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Prosidyan, Incorporated
% Ms. Janice Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K132805
Trade/Device Name: BG Morsels Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 28, 2014
Received: January 28, 2014

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K132805

Device Name

BG Morsels Bone Graft Substitute

Indications for Use *(Describe)*

BG Morsels - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. BG Morsels is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

BG Morsels is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132805